IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

IN RE:	)
AREDIA and ZOMETA PRODUCTS	) No. 3:06-MD-1760
LIABILITY LITIGATION	)

MEMORANDUM

Pending before the Court is Plaintiffs' Motion for Certification of a Dental Monitoring Class (Docket No. 577). The Court held a hearing on Plaintiffs' Motion on October 5, 2007. For the reasons stated herein, Plaintiffs' Motion is DENIED.

This action is a multidistrict litigation ("MDL") products liability case against Novartis Pharmaceutical Corporation, transferred to this Court for pretrial proceedings pursuant to 28 U.S.C. § 1407. More than two hundred eighty-five individual MDL cases are currently pending before this Court.

Plaintiffs allege that two drugs, Aredia and Zometa, both manufactured by Defendant, increase the risk of and cause osteonecrosis of the jaw ("ONJ"). ONJ is a "painful, irreversible and disfiguring disease" that can result in very serious and frightening medical conditions. Docket No. 580, p. 2. Plaintiffs bring causes of action based upon the legal theories of strict liability and negligence. Docket No. 506 (Master Class Action Complaint for Dental Monitoring). In this Motion, Plaintiffs seek class certification, pursuant to Fed. R. Civ. P. 23, of a group of Plaintiffs defined as follows:

> All persons who reside in jurisdictions that do not preclude certification of a class for dental monitoring or surveillance,[1] who are taking or took Aredia, Zometa, or both,

[1] Plaintiffs allege that these 34 jurisdictions are: Alaska, Arizona, Arkansas, California, Colorado, Connecticut, District of Columbia, Florida, Georgia, Guam, Hawaii, Idaho, Iowa, Illinois,

> who do not have a prior diagnosis of osteonecrosis of the jaw as defined by the American Association of Oral and Maxillofacial Surgeons, which is exposure of the bone in the maxilla or mandible persisting for more than eight weeks, and who have had no radiation therapy to the jaws.

Docket No. 577.

Alternatively, Plaintiffs move to certify a multi-state class for those jurisdictions which have clearly allowed medical monitoring,[2] using the model of *In re Telectronics Pacing Systems, Inc.*, 172 F.R.D. 271 (S.D. Ohio 1997). Finally, Plaintiffs move alternatively to certify a narrower class on behalf of the residents of the State of California and to certify the question of the viability of dental monitoring under Georgia law to the Georgia Supreme Court.

Defendant contends that Plaintiffs are asking for relief in the amount of $1,000 per person for 1.9 million potential plaintiffs, or a total of $19 billion. Defendant argues that a proposed class, under any of Plaintiffs' alternatives, cannot be certified because of the many individualized issues presented in each case.

CLASS CERTIFICATION

The Supreme Court has required district courts to conduct a "rigorous analysis" into whether the prerequisites of Rule 23 are met before certifying a class. *In re American Medical Systems, Inc.*, 75 F.3d 1069, 1078-79 (6th Cir. 1996). The trial court has broad discretion in deciding whether to

---

Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Oklahoma, Pennsylvania, Puerto Rico, Rhode Island, South Dakota, Tennessee, Utah, Vermont, West Virginia, Wisconsin and Wyoming. Docket No. 577, n.1.

[2] Plaintiffs allege those 13 jurisdictions to be: Arizona, California, Colorado, Connecticut, Florida, Illinois, New Jersey, Ohio, Pennsylvania, Tennessee, Utah, West Virginia and Guam. Docket No. 577, n. 2.

certify a class, but that discretion must be exercised within the framework of Rule 23. *Id*. at 1079. The party seeking the class certification bears the burden of proof. *Id*.

The strength of the underlying merits of Plaintiffs' claim should not affect the certification decision. *In re Welding Fume*, __ F.Supp.2d __, 2007 WL 2701925 at * 5 (N.D. Ohio Sept. 14, 2007). On the other hand, the Court should look past the pleadings when determining whether the requirements of Rule 23 have been met. The Court must understand the claims, defenses, relevant facts and applicable substantive law to make a meaningful determination of class certification issues. *Id*.

The issue on this Motion is *not* whether these two drugs cause ONJ or whether Defendant knew or should have known that the two drugs cause ONJ. The issue on this motion is *not* what kind of dental monitoring would best prevent ONJ. The issue on this Motion is whether to certify a class, specifically one of the classes identified by Plaintiffs in their Motion.

Thus, the Court notes that even if Defendant's own agents have recommended dental monitoring, as Plaintiffs argue (Docket No. 580), it does not *necessarily* follow that the Court should certify a class. Even if dental monitoring would help prevent ONJ, as Plaintiffs argue (*id*.), it does not *necessarily* follow that the Court should certify a class. Even if dental monitoring would aid in the collection of information for research and possible cure of ONJ, as Plaintiffs argue (*id*.), it does not *necessarily* follow that the Court should certify a class. These are matters to weigh and consider in light of all the Rule 23 factors.

The first step in determining whether a class should be certified is to decide whether the Plaintiffs have identified a class that exists and that can be precisely defined. *Perez v. Metabolife Int'l, Inc.*, 218 F.R.D. 262, 266 (S.D. Fla. 2003). A court should deny class certification where the

number of individualized determinations required to determine class membership becomes too administratively difficult. *Id*. at 269.

In this case, Plaintiffs' proposed class is open-ended, with no time limitations either forward or backward. The Court finds that there are myriad individual differences within the proposed plaintiff class which require individualized determinations as to class membership. To determine who is actually in the class as defined by the Plaintiffs, the Court[3] must determine, on a case-by-case basis, issues including (1) which product(s) the person used;[4] (2) the extent of the person's exposure; that is, the exact dosage[5] of each drug; (3) whether the person currently has ONJ as ultimately defined in this case;[6] (4) whether the person had radiation to or near the jaw; (5) when,[7] and for how long, the person took the drug(s); (6) what, if any, unique risk factors[8] the person has in his or her

---

[3] Plaintiffs' suggestion that class eligibility could be determined as part of Plaintiffs' proposed claims administration process (Docket No. 644, p. 9) is unworkable. Defendant is entitled to challenge any potential class member at the outset. The Court should not, and will not, delegate these threshold legal determinations.

[4] Generic bioequivalents of Aredia became available in 2001. Docket No. 635, p. 5. Defendant argues there is no clear or objective way to determine if a potential Plaintiff actually used the generic drug rather than Aredia.

[5] Plaintiffs' expert acknowledges that there is a threshold dosage which must be reached before any risk of ONJ occurs. Docket No. 636, Ex. 12 (Deposition of Dr. Marx), pp. 160-61 and 272-73.

[6] Defendant argues that even Plaintiff's expert has admitted there is no generally-accepted definition of ONJ.

[7] When the Plaintiff took the drug is relevant to what information was available at that time to the Defendant, to the public, to the particular physician and to the particular plaintiff.

[8] The parties dispute whether other risk factors can cause ONJ. Defendant asserts it is entitled to show a jury that individual Plaintiffs have individual risk factors for ONJ, even if Plaintiffs claim those factors do not matter.

medical history; (7) for what condition the drug was prescribed;[9] (8) what warnings were actually given — on the packaging of the product (which may not reach the patient), from the physician and/or from the pharmacist; (9) whether the person obtained additional information from dentists, research or other sources concerning the drug(s); (10) whether the person was taking other medication at the time of exposure to the drug(s); and (11) whether the person's individual risk would benefit from the specific monitoring sought in this case.

For all these reasons, the Court finds that the initial task of identifying class members weighs against class certification.

Rule 23(a) provides:

> (a) Prerequisites to a Class Action. One or more members of a class may sue or be sued as representative parties on behalf of all only if (1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class.

Fed. R. Civ. P. 23(a). If the conditions of Rule 23(a) are all satisfied, the party seeking certification must also demonstrate that it falls within at least one of the subcategories of Rule 23(b) before a class can be certified. Fed. R. Civ. P. 23(b).

The parties here do not dispute that Plaintiffs can satisfy the numerosity requirement of Rule 23(a), so the Court finds that the first requirement is satisfied.

---

[9] Plaintiffs assert that the FDA approved Aredia to treat hypercalcemia of malignancy, Paget's Disease, osteolytic bone metastases of breast cancer and osteolytic lesions of multiple myeloma. Docket No. 580, p. 14. Plaintiffs assert that Zometa is a successor drug to Aredia and was approved for hypercalcemia of malignancy, multiple myeloma and documented bone metastases from solid tumors. *Id*.

The commonality requirement deals with shared questions of law or fact. Although Rule 23(a)(2) speaks of "questions" in the plural, the Sixth Circuit Court of Appeals has said that there need only be one question common to the class. *Sprague v. General Motors Corp.*, 133 F.3d 388, 397 (6th Cir. 1998). "It is not every common question that will suffice, however; at a sufficiently abstract level of generalization, almost any set of claims can be said to display commonality." *Id*. What the Court should look for is a common issue the resolution of which will advance the litigation. *Id*.

The Sixth Circuit has further observed that the mere fact that questions peculiar to each individual member of the class remain after the common questions of the defendant's liability have been resolved does not dictate the conclusion that a class action is impermissible. *In re Welding Fume* at *11 (citing *In re American Medical Systems,* 75 F.3d at 1080). In fact, the commonality requirement has been characterized as a "low hurdle" easily surmounted. *Id*.

Plaintiffs assert that the common questions shared by all class members are (1) whether Aredia and Zometa cause ONJ; (2) whether Defendant sought to avoid liability by obscuring the ONJ issue with contrived other risk factors; (3) whether Defendant's claimed other causes are false, rendering Defendant's communications false and misleading; and (4) whether dental monitoring[10] will minimize the harm to people exposed to Defendant's drugs. Docket No. 644.

---

[10] Plaintiffs argue that the class proposed here will be prosecuting one legal claim, dental monitoring. Docket No. 580, p. 34. Yet, regardless of whether Plaintiffs characterize dental monitoring as a "claim" or as a form of relief, they cannot succeed on such a claim unless and until they establish Defendant's liability. That liability, according to Plaintiffs' Main Class Action Complaint, is based upon strict liability and negligence, including negligent failure to warn and negligence *per se*. Dental monitoring may be the "common thread" that binds the proposed class members together, as Plaintiffs assert (Docket No. 580, p. 34); but establishing strict liability and negligence, as discussed below, will vary from Plaintiff to Plaintiff.

As set forth below, the Court finds significant differences in the questions of fact and in what individual Plaintiffs will need to prove to establish liability *as to them.* Nonetheless, the Court finds that Plaintiffs' claims are all related to the same two drugs, manufactured by the same Defendant, with the same alleged general side effect (ONJ) and the same alleged course of conduct by the Defendant toward the public in general. Thus, the Court finds that Plaintiffs have met the "low hurdle" of showing common questions of law for the requirement of commonality. *See Sweet v. Pfizer*, 232 F.R.D 360, 367 (C.D. Cal. 2005).[11]

The third requirement, typicality, determines whether a sufficient relationship exists between the injury to the named plaintiff and the conduct affecting the class, so that the court may properly attribute a collective nature to the challenged conduct. *Sprague*, 133 F.3d at 399. A necessary consequence of the typicality requirement is that the representative's interests will be aligned with those of the represented group, and in pursuing his own claims, the named plaintiff will also advance the interests of the class members. *Id.*

A plaintiff's claim is typical if it arises from the same event or practice or course of conduct that gives rise to the claims of other class members, and if his or her claims are based on the same legal theory. *In re Welding Fume* at * 14. Under the typicality prong, in contrast to the commonality prong, the Court must ask whether, despite the presence of common questions, each class member's claim involves so many distinct factual or legal questions as to make class certification inappropriate. *Id.*(citing *Marquis v. Tecumseh Products Co.*, 206 F.R.D. 132, 159-60

[11] As noted in *In re Welding Fume*, other courts have easily concluded, in the context of class claims for medical monitoring, that the prerequisites of commonality were met even if the other prerequisites of Rule 23 were not. 2007 WL 2701925 at * 11.

(E.D. Mich. 2002)). Too many meaningful differences across the plaintiff class can preclude certification. *Id*.

The same individualized issues which would determine class membership, as set forth above, would also have to be part of the proof at trial. In addition, other individual issues would have to be addressed for and during the trial, including (1) which state has the most significant relation to the person's claims, for Tennessee (as the forum state) choice of law purposes;[12] (2) what is required under that state's law to prove strict liability and negligence; (3) what affirmative defenses are available to Defendant under that state's law; (4) what affirmative defenses apply to the specific Plaintiff's situation; (5) what statute of limitations applies and whether the particular Plaintiff falls within that limitation; (6) what elements are required, under the particular state's law, to establish a claim for dental monitoring; and (7) whether the particular Plaintiff can establish those elements.

In order to prove strict liability and negligence, under any state's law, Plaintiffs will have to prove causation, which is inherently an individual issue. Whether Aredia and Zometa can cause ONJ is a different question than whether Aredia and Zometa caused ONJ in a specific person. In other words, Plaintiff may not prove causation by merely showing that Aredia and Zometa can cause ONJ. Although such proof would certainly be the starting point in the causation inquiry, Plaintiffs must demonstrate that Defendant's intentional or negligent conduct proximately caused each individual Plaintiff to have a significantly increased risk of contracting ONJ, thereby demonstrating the need for dental monitoring. *See In re Welding Fume* at 16 (citing *Barnes v. American Tobacco Co.*, 161 F.3d 127, 132 (3d Cir. 1998)) and *Blain v. Smithkline Beecham Corp.*, 240 F.R.D. 179, 185

[12] Tennessee choice of law rules dictate that Tennessee courts apply the law of the state with the most significant relationship to the occurrence and the parties. *Glennon v. Dean Witter Reynolds, Inc.*, 83 F.3d 132, 136 (6th Cir. 1996).

(E.D. Pa. 2007). The answer to the specific causation issue depends upon a number of factors such as the dosage taken, the duration of the treatment, the patient's age and other characteristics, and the patient's medical history.

Moreover, Plaintiffs' failure to warn claims depend upon a number of individual factors. These drugs are typically administered by nurses, in clinics, under physicians' orders, and what, if any, warnings were given to the patient varies from individual to individual. In addition, Defendant argues that if a particular Plaintiff's physician would not have changed the course of treatment no matter what warning was given, then there is no proximate cause as to that Plaintiff.

Defendant would also be entitled to raise certain defenses, depending upon the applicable state law, which must be evaluated on a case-by-case basis. For example, under Tennessee law, the Defendant might raise comparative fault as a defense to negligence. Proving comparative fault, or the lack thereof, would necessarily involve individualized issues. The case involving a Plaintiff against whom such a defense was raised would be significantly different from that involving a Plaintiff against whom no such comparative fault was raised. The pertinent states have different laws on how comparative fault applies, whether contributory negligence otherwise applies, and what effect, if any, assumption of the risk may have. Furthermore, the individual defenses, including the "learned intermediary" defense raised by Defendant, vary from Plaintiff to Plaintiff.

Finally, the laws concerning medical/dental monitoring vary from state to state. Plaintiffs seek a class to include all states where medical monitoring is not expressly prohibited. To certify such a class, the Court would have to "predict" the law in certain states which have neither expressly recognized nor prohibited medical monitoring. Where medical monitoring has been recognized as a cause of action or as a form of relief, there are differences in what elements the states require to

prove such a claim. *In re Welding Fume* at * 7. Some states recognize medical monitoring as an element of damages when liability is otherwise established, while other states recognize medical monitoring as an independent cause of action. *Id*. Some states require proof of a present, physical injury to obtain medical monitoring, and some do not. *Id*.

Even under the *Telectronics* model proposed by Plaintiffs, individual issues of fact preclude certification of the class. Whether it be 34 jurisdictions or 13 jurisdictions or even one jurisdiction, the individual fact issues remain. Trying all California plaintiffs as a class or certifying a question to the Georgia Supreme Court, as Plaintiffs suggest, would not solve the other individual issues, such as causation or individual defenses, which preclude class certification.

For all these reasons, the Court finds that Plaintiffs' proposed class does not meet the typicality requirement of Rule 23(a).

The last requirement of Rule 23(a) is that the representative parties will fairly and adequately protect the interests of the class. The Sixth Circuit has articulated two criteria for determining adequacy of representation: (1) the representative must have common interests with unnamed members of the class, and (2) it must appear that the representatives will vigorously prosecute the interests of the class through qualified counsel. *In re American Medical Systems, Inc.*, 75 F.3d at 1083. This requirement raises issues of the adequacy of class counsel and the existence of any conflicts of interest among potential class members. *Appleton v. Deloitte & Touche, L.L.P.*, 168 F.R.D. 221, 227 (M.D. Tenn. 1996).

There does not appear to be any dispute that proposed class counsel are adequate to prosecute this action. For the same reasons that the Court has found typicality to be missing, however, the Court finds that there would be conflicts of interest between the class representatives

and the proposed class and conflicts among potential class members. As shown above, the individual differences between the two class representatives and the members of the proposed class[13] (and also among the various potential class members themselves) weigh against any argument that the representative parties will fairly and adequately protect the interests of the class.

When courts have determined that typicality is absent because there are too many divergent individual issues among plaintiffs, they will also hold that adequacy of representation is lacking. *Sweet*, 232 F.R.D. at 370. The Court finds that Plaintiffs here do not meet the adequacy requirement of Rule 23(a).

For all these reasons, the Court finds that Plaintiffs have not satisfied the basic class action requirements of Rule 23(a). The proposed class definition itself reflects the individual issues needed to be determined, just to identify members of the class: All persons *who reside in jurisdictions that do not preclude certification of a class for dental monitoring or surveillance*; *who are taking or took Aredia*, *Zometa*, *or both*; *who do not have a prior diagnosis of osteonecrosis of the jaw* (as defined by the American Association of Oral and Maxillofacial Surgeons, which is exposure of the bone in the maxilla or mandible persisting for more than eight weeks); and *who have had no radiation therapy to the jaws.*

Plaintiffs argue that the industry, even Defendant itself, has recognized the desirability of dental monitoring. As the court stated in *In re Welding Fume*, however: "That the industry has acknowledged, at least in part, the legitimacy of plaintiffs' prayer, however, is not tantamount to the

[13] Defendant argues that the class representatives have no standing to raise issues as to states other than their own.

existence of a basis upon which this Court can conclude that the plaintiffs are entitled to pursue their medical monitoring claims as a class." *In re Welding Fume* at * 24.

Having determined that Plaintiffs do not meet the requirements of Rule 23(a), the Court need not address the additional requirements of Rule 23(b).

CONCLUSION

For all these reasons, Plaintiffs' Motion for Class Certification (Docket No.577) is DENIED. The Court expresses no opinion on the ultimate issue of liability in this case.

IT IS SO ORDERED.

TODD J. CAMPBELL
UNITED STATES DISTRICT JUDGE